> Others would require measurement over a period of time. For example, how long would be a working bout, how long might be rest breaks between such bouts of keyboard operation. How many key strokes were performed over a period of time.
>
> Perhaps even how large are the actual activation forces being applied by the subject as opposed to design values, which are not necessarily the ones that operate as used.
>
> So there are some issues that can be resolved by observation. There are some issues that need to be resolved by measurement.

D.I. 359 at 170-71.

IBM contends that Kroemer's conclusions are unreliable because: (1) his methodology was unscientific; n19 (2) he was unable to cite a single study which demonstrates that the use or design of keyboards results in some injury (such as CTS, as in the case at bar); and (3) he did not describe any specific design defect in the IBM keyboard which *caused plaintiffs' injuries*. D.I. 309 at 13.

n19 As evidence of Kroemer's unscientific methodology, defendant highlights the "catch-basin" nature of his report on "keyboard design," "keyboard use," and "cumulative trauma disorders," whereby a piece of literature was not required to discuss both "keyboard design" and "cumulative trauma disorders" to be included in his reports. D.I. 309 at 12, D.I. 310, Ex. A-322 (citing Flowerdew, R.E. and Bode, O.B., Tenosynovitis in Untrained Farm-Workers, Medical Memoranda, Bawan [sic] Medical Journal (1942)); (see also, D.I. 310, Ex. A-329) (citing Conrad, R. and Longman, D.J.A., Standard Typewriter v. Chord Keyboard-An Experimental Comparison, 8 Ergonomics 77-88 (1965)). Further, criticisms by IBM of Kroemer's unscientific approach to the issue at hand center on the witness' deposition response (cited in relevant part) to the inquiry of whether any of the examined literature concludes that keying causes "cumulative trauma disorders":

> . . . my point of interest in this whole procedure is what are the ergonomic aspects of keyboards that may lead -- that have suspected symptoms or, in fact, may have been fact to [sic] lead to cumulative trauma disorders. If we then depart with the -- depart from that ergonomic point of view, all we need to do is start, in fact, in page 1 of Exhibit No. 6 [Kroemer Supp. Report] and read the synopsis of what Osler said in 1892. And if you read this, it says: The continuous and excessive use of muscles in performing a certain movement may be followed by an irregular, involuntary spasm, cramp and so forth. How much more clearly can it be established . . . that more than one hundred years ago that certain activities such as might be required on a keyboard can constitute a continuous and excessive use of muscles that result in a disorder. And that will be a typical example in the way of which I would try to answer your question in terms of what does [sic] ergonomists read out of that literature.

D.I. 309 at 13; D.I. 310, Ex. A-206.

[*51]

Having set forth Kroemer's methodology and with the acknowledgment that Kroemer is an expert in his field, this Court will now determine whether it satisfies Daubert/Paoli II, with consideration of the Schneck court's analysis on the matter. See Schneck Op. at 21-25.

(1) Daubert/Paoli II Factors

(i) Does the Methodology Consist of a Testable Hypothesis?

Defendant does not challenge the testimony of Kroemer's hypothesis, that "the relation between [cumulative trauma disorders] and design and use of keyboards as input devices was well established." Rather, defendant argues that Kroemer's *conclusions* are unreliable, in light

of his unscientific methodology, his inability to cite a single study demonstrating that the use or design of keyboards causes some injury (such as CTS, as in the case at bar), and his further failure to describe any specific design defect in the IBM keyboard which caused plaintiffs' injuries. D.I. 309 at 13. Accordingly, this factor will weigh in favor of the admissibility of the proffered testimony.

(ii) Has the Methodology Been Subject to Peer Review?

At the *in limine* hearing in Schneck, as well as in this matter, Kroemer [*52] testified that the particular reports at issue (his pre-August 1995 reports) have not been subject to peer review. See Schneck Op. at 21 (citing Kroemer Tr. at 41); D.I. 359 at 60. Further, he was uncertain whether the methodology leading to his conclusion has been utilized or recognized by others. Id. (citing Kroemer Tr. at 45-46); D.I. 359 at 116-17. While with particular respect to design defect, several scientific articles relied upon by Kroemer were purportedly subject to peer review, Kroemer's more recent *in limine* testimony never addressed whether his analysis or methodology has been followed by others in his field. n20 As such, this factor militates against the admissibility of the proffered testimony.

> n20 To the extent, if at all, that the August 1995 report is dependent upon his prior report and abstracts, Kroemer is still uncertain whether his methodology has been followed within his profession.

(iii) Is There a Known or Potential Rate of Error?

No known or potential rate of [*53] error in Kroemer's methodology has been provided and therefore, the Court cannot evaluate this element. As a result, this weighs against the admission of the proffered testimony.

(iv) Were There Standards Controlling the Technique's Operation?

In his analysis, Kroemer accepts the conclusions reached in the various articles collected by him and compares them with his understanding of how the body reacts to repetitive exertions of the kind described in the articles. The Court does not regard this as a "standard." Therefore, this factor counts against the admissibility of Kroemer's proffered testimony.

(v) Is the Methodology Generally Accepted?

As previously discussed, Kroemer is unaware of any followers of his methodology. See Schneck Op. (citing Kroemer Tr. at 45-46); D.I. 359. Nor have plaintiffs identified any such followers. This factor thus weighs against the admissibility of his proffered testimony.

(vi) Is There a Relationship Between the Technique and Other Methods Established to be Reliable?

No clearly definable technique has been provided enabling this Court to ascertain the relationship between such a technique and other methods of established reliability [*54] for his analysis of state-of-the-art and design defects. Accordingly, this component weighs against the admissibility of proffered testimony.

(vii) Are the Qualifications of the Expert Based Upon the Methodology Appropriate?

Defendant has not challenged Kroemer's qualifications. This factor therefore supports the admission of the proffered testimony.

(viii) Non-Judicial Uses

No distinct parameters have been identified to determine whether Kroemer's methodology would have any application outside of the current judicial setting. As a result, this consideration also weighs against the admissibility of his proposed testimony.

(ix) Other Factors

As previously noted, Kroemer admitted in his deposition that scientists' current knowledge about the hypothesized relationship between keyboard design/use and cumulative trauma disorders is limited. D.I. 310, Ex. A-290-91, 463-64. Moreover, plaintiffs' proposed expert has failed to cite a single study which demonstrates that use or design of keyboards causes some injury (or, as is relevant to this case, carpal tunnel syndrome). Notwithstanding his incertitude and absence of literative support, Kroemer maintains that the "relation" [*55] between "cumulative trauma disorders" and "design and use of keyboards" is "well established." D.I. 310, Ex.A-352. Although a finding that an expert's opinion is unreliable cannot be made merely because the concept is novel or differs from that of other experts, Kroemer nonetheless must provide a detailed rationale for reaching his firm conclusion, and in so doing, address how he overcame the aforementioned concerns. Without such evidence, this factor militates against the admissibility of the proffered testimony.

(x) Conclusion

This Court concurs with Schneck's holding that the Daubert/Paoli II analysis weighs decisively in favor of excluding the proffered testimony. [HN18] Daubert's standards are clear: "the expert [must] testify to scientific knowledge -- conclusions supported by good grounds for each step in the analysis -- meaning that any step that renders the analysis unreliable under the *Daubert factors*

renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology." *Paoli II, 35 F.3d at 745* (footnote omitted) (emphasis in original). In light of his unscientific [*56] methodology and inability to produce a single study demonstrating that the use or design of keyboards causes some injury (such as CTS), Kroemer's conclusions must be deemed unreliable.

(2) Fit

[HN19] *Fed. R. Evid. 702*'s third requirement -- that the evidence is relevant or "fits" under the facts of the case- also must be satisfied before an expert's proffered testimony may meet the Daubert test.

In the case at bar, Kroemer's testimony has been offered for the proposition that keyboard use can cause "cumulative trauma disorders," defined as a "collective term for syndromes characterized by discomfort, impairment, disability or persistent pain in joints, muscles, tendons and other soft tissues, with or without physical manifestations." D.I. 310, Ex. A-314. Yet, Kroemer has offered no scientific research which proves that keyboard use can cause the medical conditions claimed in this action. Furthermore, while Kroemer did offer some specific criticisms of the generic QWERTY keyboard design and proposed what is theoretically a more ergonomically appropriate alternative (i.e., the split keyboard design), no evidence was proffered that such an alternative design actually reduces the incidence [*57] of any musculoskeletal disorders purportedly associated with repeated keyboard use. Accordingly, as. in Schneck, this Court finds that Kroemer's testimony regarding the "defective" design of keyboards and its resulting adverse medical implications must be excluded, where there is no "connection between the scientific research or test result to be presented, and particular disputed factual issues in this case." n21 *Velasquez, 64 F.3d at 850* (quoting *Downing, 753 F.2d at 1237)* See also Schneck Op. at 25.

n21 In Dennis v. Pertec Computer Co., a similar product liability action, plaintiffs proffered Kroemer's expert testimony regarding "the relationship between the biomechanics of keystroking and upper extremity disorders." *927 F. Supp. 156, 160 (D.N.J. 1996).* The court excluded Kroemer's testimony, concluding that "Kromer's (sic) unrecorded mental methodology amounts to nothing more than unsupported speculation." *Id. at 161.* While plaintiffs in the case sub judice argue that the Dennis court's decision was "clearly overreaching" (D.I. 322), and that the record indicates the reliability and peer review of Kroemer's research and opinions, this Court holds otherwise for the reasons discussed herein.

[*58]

(d) Conclusion

Based on the foregoing analysis, this Court recommends Dr. Kroemer's testimony be excluded in its entirety.

B. Dr. Laura Punnett

Laura Punnett, Sc. D., is an occupational epidemiologist and ergonomist. In Schneck, as in the case at bar, plaintiffs offer her opinion to establish general causation between VDT (video display terminal) use and "musculoskeletal disorders." While also asked to opine on causation with respect to the Schneck plaintiff's individual claim, Punnett serves as a "generic" expert in the case at bar, where her opinion does not specifically address either Allen's or Bower's particular assertions of injury. Indeed, Punnett's report submitted for the purposes of this action is identical to that considered in Schneck v. IBM, with the current parties utilizing, her deposition testimony from the earlier case, supplemented by her November 27, 1996 *in limine* hearing testimony. (Punnett *In Limine* Hearing, November 27, 1997, D.I. 350).

According to her *in limine* testimony, Punnett began her research by conducting an unbiased literature review for articles directly bearing on video display terminal use and upper extremity [*59] musculoskeletal injury, n22 the standard operating procedure in the scientific community. Each study was then reviewed to ensure that it met the minimum quality of methodological criteria for a sound epidemiological study. To wit, Punnett considered: (1) the potential for selection and information bias; (2) whether potential confounders were measured and included in the analysis; (3) the size of the study and the statistical power involved; and (4) the nature of the contrast and exposure, and whether there was likely to be a big enough spread and exposure to plausibly show a difference in health effects, if one existed. Punnett then grouped the studies according to their "strength," ensuring that even the weakest met the minimum threshold of the search criteria. The studies were next grouped systematically, with Punnett organizing them by body region and identifying each study's respective results for the assessed physical dimensions of exposure. D.I. 350 at 4-13.

n22 This review was conducted via a key word search on a computerized database of literature on occupational safety and health, and supplemented by consultation with other experts in the subject field. D.I. 350 at 11-12.

[*60]

Punnett testified that she did not conduct a meta-analysis of the studies' data -- that is, "a calculation of common or pooled odds ratios or relative risk estimates" *sometimes* made by epidemiologists. D.I. 311, Ex. A-594. She did, however, examine the data of each study for its consistency and evaluated each study on its own merits. Punnett further conducted independent analyses of the internal data of the selected studies, including comparison to an external source of data. Specifically, Punnett used the set of data for the low force, low repetition group in the Silverstein papers (part of the included scientific literature) to estimate gender-specific expected rates of disease, and then standardized the expected rate to the mix of male and female workers in each of two other prominent studies. She further calculated gender-standardized odds ratios -- estimates of relative risk -- for the health end point (which in one case was the hand-wrist disorders defined by symptoms and physical examination, and in two other cases was for the symptom-based case definition). A comparison of the age distribution amongst all the populations also was conducted. D.I. 350 at 23-34, 36-43. [*61]

With regard to supplemental external analyses, Punnett compared an external "background" group of people who were employed in jobs that were measured quantitatively and objectively and found to be "low" in the manual force and repetition requirements associated with job duties. n23 Establishing such a background level of disease -- i.e., the rate of disease expected in the general population with minimal or no exposure to the relevant risk factors -- permits the determination of whether an elevation of the disease and its symptoms are, in fact, a consequence of risk factor exposure. D.I. 350 at 23-34,36-43.

n23 This reference group was utilized by one of the studies upon which Punnett relied. D.I. 350 at 23-34, 36-43.

Based on twenty studies n24 found in the open epidemiological literature, Punnett concluded in Schneck (as well as in the matter under consideration) that such:

> literature provides reasonably convincing evidence that VDT work *per se*, whether measured in hours worked per week, years [*62] duration of employment, typing speed, or intensity of keying (data entry vs. interactive tasks), is causally related to an elevated risk of musculoskeletal disorders [and related soft-tissue disorders]. n25 n26

D.I. 311, Ex. A-652.

In reaching her conclusion on the causation of keyboard induced injury, Punnett discussed eight criteria, including types of error and bias, commonly considered by epidemiologists in determining causality: (1) random misclassification of exposure or of health status; (2) selection bias; (3) information or recall bias; (4) confounding; (5) temporal sequence of cause and effect; (6) strength of association; (7) exposure-response relationships; and (8) biological, plausibility and external validity. D.I. 311, Ex. A-632-37, Ex. A-652-54.

n24 Although Punnett began her review with twenty studies, she relied on only eleven. Of those, Punnett deemed the following seven studies to have "no or only very minor methodological flaws that might affect interpretation of their results": *LA Times, Newsday, US West, Knave, Rossignol*, and *Sauter. D.I 311, Ex. A-651, Ex. A-655-58*. The remaining four of the eleven, conducted by *Hunting, Kamwendo, Maeda*, and *Starr*, "had relatively minor weaknesses, not serious enough to invalidate them completely or that only affected some of the study findings." D.I. 311, Ex. A-651, A-656-59.

[*63]

n25 Under Punnett's definition, such disorders are "a group of clinical syndromes including nerve compression disorders (such as carpal tunnel syndrome), tendon inflammations and related conditions (tenosynovitis, epicondylitis, bursitis of the shoulder, etc.), as well as non-specific pain or paresthesia and conditions that some clinicians describe as myositis, fibromyalgia, focal dystonia, and other diagnoses that are less well standardized." D.I. 311, Ex. A-629. Defendant argues that Punnett's definition excludes any reference to, or discussion of, a scientifically defined disease entity. D.I. 309 at 14.

n26 Punnett's additional analyses with the aforementioned low-risk external group displayed an even stronger contrast in risk of hand and wrist symptoms and physical findings between the exposed group and "non-exposed," low-risk external group. D.I. 350 at 23-34, 36-43.

Rather than argue that the set of criteria employed by Punnett in reaching her conclusion is unsound, IBM

submits that Punnett's opinions should be excluded because *none* of the eleven "strongest" studies relied upon [*64] specifically discusses an association, much less a causal relationship, between CTS and video display terminal use. D.I. 309 at 19. Moreover, the following methodological flaws in the studies cited "render [Punnett's] opinions regarding causation unreliable and unhelpful to the trier of fact": (1) the studies discuss subjective symptoms rather than disease entities; (2) the studies have poorly conceptualized objectives -- i.e., ones that are unclear and not stated quantitatively; (3) all but one of the twenty studies are cross-sectional in design, thereby potentially limiting results to the identification of an exposure and an outcome, rather than a cause and effect relationship; (4) almost all of the cross-sectional studies are self-reported, and consequently susceptible to study subject misclassification and over-report "response bias"; (5) two of the top eleven studies have potential bias in subject selection, therefore limiting the studies' conclusions; (6) all of the eleven top studies fail to take into account the fact that "musculoskeletal disorders" are not unique to office and manufacturing workers; and (7) the studies do not account for other possible causes. D.I. 309 at [*65] 15-19. n27 Finally, defendant maintains that Punnett's literature review conclusions are vague and unsubstantiated, as evidenced by the doctor's own admission that no meta-analysis or calculation has been conducted, but yet she "estimates" that the "relative risk of shoulder, arm and hand disorders is at least two for the keyboard work of at least four hours per day . . . ." D.I. 309 at 19, D.I. 311, Ex. A-652. As Punnett is unable to quantify the relative risk of use of keyboards versus the "risk" of any person within the general population getting a musculoskeletal disorder, it is impossible for a jury to conclude that the keyboard user's "risk" presents an unreasonable risk of harm or one so probable as to render the instrument as defective. D.I. 309 at 19-20. In light of these considerations, and where the epidemiologist fails to establish an association between the injuries allegedly suffered by plaintiffs and any amount of typing, it must be held that Punnett's conclusions are "unfounded and unreliable and . . . completely unhelpful to the trier of fact" D.I. 309 at 20.

n27 In Schneck, the defendant made the same arguments now cited. See Schneck Op. at 27-28.

[*66]

In support of this contention, defendant submits corroborating affidavit testimony by expert epidemiologist Dr. Dimitrious E. Trichopoulous ("Trichopoulous"). n28 Trichopoulous, a physician and epidemiologist, is currently the Chairman of the Department of Epidemiology at the Harvard School of Public Health, as well as the Director of the Center for Cancer Prevention at Harvard. More than one hundred of his professional publications focus on occupational or environmental epidemiology. Aff. of Trichopoulous at P1.

n28 Trichopoulous' testimony stems from the Schneck case, during which IBM offered the doctor's expert opinion to challenge the quality and reliability of the studies upon which Punnett based her report at issue. D.I. 334 at 15. Currently submitted correspondence between the parties in that action indicate that the Schneck plaintiffs chose to forego cross-examination of Trichopoulous in favor of submitting a responsive supplemental report by Punnett herself. D.I. 344, Ex. D-G. In the case at bar, defendant included the aforementioned correspondence as exhibits to the Reply Brief (D.I. 334, Ex. D-G), but inexplicably failed to submit Trichopoulous' actual affidavit and deposition until this Court queried as to their location in the exhibits, where the documents were alluded to on a number of occasions and are apparently relevant to the matter at hand. While it may be argued that defendant's late submission of these materials is inappropriate, the Court will consider this evidence, which has no docket entry number and is instead cited as "Aff. of Trichopoulous," deeming such latitude in the interest of justice. Attached to Trichopoulous' affidavit dated January 30, 1994 as Exhibit A is a 17-page assessment of the evidence concerning a possible link between keyboard operation and data entry tasks and musculoskeletal disorders, which includes his criticism of Punnett's analysis, as Exhibit B, his deposition of September 13, 1994 and as Exhibit C a supplement dated July 7, 1995 to his original report contained in Exhibit A.

[*67]

In formulating his "assessment of the evidence concerning a possible link between keyboard operation and data entry tasks and musculoskeletal disorders in video display terminal-related work," Trichopoulous reviewed Punnett's report, as well as the twenty studies upon which she based her conclusions. Aff. of Trichopoulous at P2-3. As a result, IBM's expert unequivocally disagrees with Punnett's conclusions, based on differences in both the basic premises n29 and the weighing and interpretation of the existing evidence. Specifically, Trichopoulous states the following criticisms, in addition to providing a brief critique of each individual study:

. . .It is essential to note that the musculoskeletal disorders under consideration in Dr. Punnett's report and the relevant studies do not concern disease entities or clinical syndromes as defined in the medical and epidemiological literature, but rather a collection of symptoms (subjective) and occasionally signs (objective). *I submit that the concerned scientists should focus on the understanding of the etiology of a scientifically defined disease entity, rather than on the attribution of symptoms that may represent physiological* [*68] *responses to extreme exposures of particular organs or systems in the process of particular occupational activities.* I have little difficulty accepting that any occupation involving intense use of any particular organ will be associated with symptomatology from that organ; the problem is whether symptomatology can develop into an independently defined and generally recognized (World Health Organization 1977) disease entity.

* * *

Aff. of Trichopoulous, Ex. A at 3-4.

No study has examined individuals with clearly defined disease or an a priori determined clinical syndrome (Morris 1975). Five of the studies (Bernard et al. 1992, Hunting et al. 1981, Kamwendo et al. 1991b, Nathan et al. 1988, Onishi et al. 1982) have used some objective examination or measurement and these measurements were "negative" (indicating no association) in two studies (Bernard et al. 1992, Nathan et al. 1988), equivocal in two others (Hunting et al. 1981, Kamwendo et al. 1991b), and positive in only one (Onishi et al. 1982).

Eighteen studies have used questionnaire-ascertained symptomatology as outcome variables and of these nine were reported as clearly or suggestively positive (Bernard et [*69] al. 1992, Burt et al. 1990, Duncan and Ferguson 1974, Heyer et al. 1990, Kamwendo et al. 1991a, Maeda et al. 1980, Rossignol et al. 1987, Smith et al. 1981, Stellman et al. 1987) whereas in three studies (Hunting et al. 1981, Kamwendo et al. 1991b, Knave et al. 1985) the results were equivocal and in six studies (Fahrbach and Chapman 1990, Hales et al. 1992, Sauter et al. 1991, Starr et al. 1989, Starr et al. 1985, Star 1984) the results were essentially "negative" (no association). *It appears that VDT work has not been shown to be causally associated with an a priori defined disease or clinical syndrome, and there is very little evidence for an association based on objective pathophysiologic measurements.* By contrast, studies based on questionnaire-ascertained symptoms are more often than not positive for an association between VDT related work and musculoskeletal symptomatology, although the results are by no means uniform across studies. When associations are reported they are usually weak, with odds ratios below 2 and squared partial correlation coefficients below 0.05. Indeed, these associations with VDT related work, are, as a rule, weaker than the corresponding associations [*70] with gender (e.g. Knave et al. 1985) or variously operationalized psychosocial variables (eg. Burt et al. 1990, Hales et al. 1992).

The existing evidence does not support a casual link between VDT related work and a clinically defined musculoskeletal disease or syndrome. There is circumstantial evidence for an association between VDT related work and subjective musculoskeletal symptomatology, but it is difficult to establish whether, and to what extent, the latter association reflects a psychosocially modulated selection process.

Biomedical considerations and other paradigms indicating that excessive functioning can lead to adverse symptomatology suggest that VDT related work may indeed generate musculoskeletal symptoms, although there is no evidence that these symptoms are based on objectively ascertainable pathology or otherwise objectively defined clinical disease. The odds ratios linking VDT related work with musculoskeletal symptoms are generally below 2 and they are, as a rule, lower than those reflecting the influence of several demographic and psychosocial variables.

Aff. of Trichopoulous, Ex. A. at 11-13 (emphasis added) (internal citations omitted).

> n29 According to Trichopoulous' deposition testimony, the doctor characterizes the aforementioned differences in basic premises as what he considers to be the lack of an independently defined and generally recognized disease entity that is being studied, as well as the criteria for causation as they were applied in a particular situation. Aff. of Trichopoulous, Ex. B at 62.

[*71]

In a supplement to the previously cited report, Trichopoulous expands on his critique of the Punnett report, asserting, in relevant part:

> . . . There is extensive literature on the methodology for quantitative summarization of study results frequently referred to as meta-analysis. Most researchers agree that meta-analysis plays a central role in the summarization of *randomized clinical trials*. The characteristics of clinical trials that make them amenable to meta-analysis are: (a) they refer to a disease; (b) they focus on an agreed explicit outcome as, for example, survival or metastasis-free time; (c) the randomization process allows control of both identifiable and elusive confounding factors since, within the constraints of chance, confounding factors are equally distributed among persons exposed and non-exposed to the treatment under evaluation; (d) selection forces are accommodated through randomization, complete follow-up and allowance for competing causes for the outcome under study (e.g. death); (e) information bias is accounted for through blinding of both study participants and investigators (double-blind, placebo-controlled studies).
>
> By contrast, epidemiologist [*72] are divided on the utility of meta-analysis for *observational (non-expedmental) investigations:* some consider it useless or even misleading, whereas others believe that it can provide an additional insight to what can be obtained from critical evaluation of individual studies. However, most epidemiologists would agree that meta-analysis is a blunt tool in observational (non-experimental) research, and can only be useful if it is based on the sound epidemiological studies that had similar designs, evaluated similar exposures, focused on similar outcomes, addressed similar sets of potential confounders and have excluded with reasonable confidence selection and information bias.
>
> In this light, it is clearly unrealistic to attempt a proper meta-analysis of the studies that have examined the relation, if any, between keyboard operation and musculoskeletal disorders. . . . The operational definition of exposure(s) varies by study, from meat-cutting, to cake decoration, to operating posture, to job dissatisfaction, to psychosocial work environment, to video display terminal work; the outcome varies from self-reported discomfort, to (unadjusted for age) median nerve sensory velocity, [*73] to (rarely) clinically indicated carpal tunnel syndrome, to *ad hoc* defined conditions "cumulative trauma disorder" (notwithstanding the absence of evidence of trauma); confounding factors are inconsistently considered and inadequately addressed; selective participation is frequently acknowledged but the resulting bias is rarely evaluated; scant attention is paid to the high likelihood for information bias; and different measures of alleged effect are used, depending on study circumstances and expertise of the investigators (prevalence ratio, odds ratio, incidence ratio, difference of mean values, etc.).
>
> * * *

Aff. of Trichopoulous, Ex. C. at 1-2.

> It is generally acknowledged that [HN20] establishment of causation hinges either (1) on experimental evidence from humans or an appropriate animal model (neither of which is at present available for the issue under consideration) or (2) more frequently, on observational human evidence ascertained through epidemiological studies. In strict terms, none of the 20 studies reviewed by Dr. Punnett in her 1993 report is a bona fide epidemiologic investigation, and none has been reported in a peer-reviewed epidemiologic journal (books, [*74] reports, and conference proceedings are not considered as peer-

reviewed publications). This does *not* indicate that these studies are of no value: they do highlight ergonomic issues and relevant psychosocial factors and they may even help to identify the exposure and outcome parameters that deserve proper epidemiologic scrutiny in subsequent investigations. Only the three recent papers by Bergqvist can be considered as epidemiological and their results do not provide support for an overall association between video display terminal work and musculoskeletal problems.

In rare occasions, associations are so strong that causality may be established even when the data were generated from imperfect studies. However, when a causal link is absent, weak, or questionable the empirical evidence should be based on demonstrably valid studies and should be supported by convincing biological arguments. With respect to the alleged link between keyboard operation and musculoskeletal disorders none of these conditions is met. Meta-analysis can summarize valid data but it is not a remedy for data of poor or questionable validity.

The attempts of Dr. Laura Punnett to derive summary quantitative [*75] **estimates from the studies she has reviewed are grossly inadequate and, in fact, misleading. This does *not* imply that Dr. Punnett lacks the necessary expertise to undertake a meta-analysis; on the contrary, I believe that Dr. Punnett is a qualified and competent colleague. However, the studies on VDT work and musculoskeletal disorders are so diverse in design, have so limited control on information bias, focus on so different outcomes and use so different effect estimators that no methodology can abstract a reasonably meaningful conclusion for the issue under investigation. The only statement that can be made is that studies that have stronger methodological safeguards and use more objective outcome measurements tend to show no association between VDT work and musculoskeletal disease in the upper extremities- and *vice versa*.**

Aff. of Trichopoulous, Ex. C at 6-7 (emphasis in original).

In response to these criticisms, plaintiffs have provided the affidavit of Dr. Stephan Zoloth (D.I. 327, Ex. 40), a professor of Epidemiology and Public Health at Hunter College in New York, as well as the Director of Hunter College Center for Occupational and Environmental Health. [*76] n30 D.I. 327, Ex. 40 at P1. This affidavit originally was submitted in the Schneck case and is now proposed for the same purpose.

> n30 While defendant in this action argues that the Schneck Court improperly considered Zoloth's testimony, where the expert earlier had been withdrawn by plaintiffs in that case, this Court finds that plaintiffs Allen and Bowers properly submitted Zoloth's affidavit for consideration on the issue of the admissibility of Punnett's expert witness testimony.

As part of his professional activities, Zoloth acts as a peer reviewer for the American Journal of Public Health and the American Journal of Industrial Medicine, customarily reviewing articles submitted to these periodicals for publication. Id. at P2. According to his affidavit, Zoloth is familiar with Punnett's Report at issue, as well as the literature reviewed by Punnett therein. Id. at 3. Regarding IBM's criticisms of Punnett (in particular, the studies relied upon by her), Zoloth provides the following comments: [*77]

> 16. Quality of the Studies
>
> First, it is important to note that Dr. Punnett's review is not restricted to just the 20 VDT studies. Indeed, the non-VDT studies which discuss the established economic risk factors (force, repetition, awkward posture, . . .) which are also present in keyboard use, are important to consider. However, even focusing on just the VDT studies, it is clear that they are all either peer reviewed or government issued, and are all authored by reputable scientists. As such they are of sufficient quality to allow for Dr. Punnett's evaluation.
>
> 17. Symptoms Reported
>
> To the extent that the researchers in the cited studies discussed symptoms reported by the subject populations, this is a

proper and common feature of such occupational health studies. Of course, in the methods sections of various of the reports, the researchers discuss the symptom complexes being studied and how they relate to defined injuries and disorders. n31 Accordingly, they do not present an obstacle to Dr. Punnett's evaluation. Rather, the studies' authors are assessing different symptomatology to determine the prevalence of work-related musculoskeletal disorders n32 in the [*78] various populations. Again, this is entirely proper. Moreover, while symptomatology may be viewed as a surrogate for disease, it can also be seen as a precursor. This makes its consideration entirely proper.

18. Statistical Association v. Causation

Within any particular study on any subject (within the field of epidemiology) the association of exposure and outcome is properly noted by the researcher. It is, however, within the larger scope of a comprehensive review -- such as that performed by Dr. Punnett -- that findings of causation are properly discussed. The tests for such conclusions are the well-established epidemiological criteria set out in the beginning of Dr. Punnett's report (pp. 4-10). Since she has followed these criteria, it is entirely proper for her -- especially giver (sic) her qualifications and experience -- to draw conclusions based upon such a review. Indeed, the studies, being of sufficient quality, properly lend themselves to such findings. While IBM's lawyers may review the studies and (assuming they follow the proper criteria) come to different conclusions, that does not mean that the studies do not support Dr. Punnett's conclusions. In fact, they [*79] do.

19. Dr. Punnett Acknowledges the Limitation of the Studies in Her Review

Any good and credible epidemiologist will be the first to admit that no study or review is perfect. In fact, it is expected of epidemiologists that they will fully and forthrightly address the weaknesses in their work. Dr. Punnett has properly done this. This in no way impairs her credibility. In fact, just the opposite is true. Moreover, it does not detract from the reliability of her work. Such acknowledgment simply puts into proper context the scope of the work and its limitations. None of those (properly) discussed by Dr. Punnett invalidate or weaken her conclusions.

20. Cross-Sectional Design

Cross-sectional studies are valid and generally accepted study designs in epidemiology and are properly considered in a review such as Dr. Punnett's. It is true that a potential limitation inherent in such a design is the subject of temporal relationship between exposure and outcome, if not properly considered and controlled for. The authors of the subject studies acknowledge this, as does Dr. Punnett, who adequately deals with this subject in the body of her report as well as in Table 1. [*80] Accordingly, it does not impair the ability to find a causal relationship in this context.

21. Self-Reporting

Use of questionnaires to elicit information concerning the outcome variable in an occupational epidemiological study is standard and well accepted in the field. While IBM's lawyers point to the potential for over-reporting, there is just as great a likelihood of under-reporting, as active workers may choose not to report outcomes for fear of jeopardizing their employment. Moreover, and on a related note, one should consider that the "healthy worker effect" (sick/injured workers are selectively removed from the studies population) will mask the true effect of the exposure.

22. Bias

As noted above, no study is perfect or without any potential bias or confounding. IBM's lawyers point to Dr. Punnett's observation that two of the twenty VDT studys [sic] contain potential selection bias, and are critical of her using those studies as part of the bases for her conclusions. This criticism is not well founded. Firstly, as Dr. Punnett properly points out, selection bias can affect results in either direction. Moreover, there is no indication

> in these two studies [*81] whether this bias is active and to what extent. However, in all events, it would be improper to disregard the findings of these studies as advocated by IBM's lawyers. Rather, Dr. Punnett properly considers them -- acknowledging their potential limitations -- in viewing the whole picture presented by the entire literature.
>
> 23. Confounding
>
> Again, no study is perfect or completely free of possible confounding. While many of the VDT studies control for some confounding factors some do not. Methodologically, this is properly noted and dealt with by Dr. Punnett in her report and in Table 2. Having done so, it is up to the reviewer to form a professional judgment as to whether or not the potential confounding precludes the drawing of conclusions. Dr. Punnett has done this. While IBM's lawyers may disagree with this conclusion, there is no reasoned basis to disregard Dr. Punnett's judgment.

D.I. 327, Ex. 40 at 5-9.

> n31 In Schneck, Zoloth argues that "the IBM lawyer is mistaken in asserting that epidemiology can only concern itself with 'disease entities.' While the symptom complexes reported in several of the studies represent distinct 'disease entities' (with specific I.C.D. codes), epidemiology does apply to many real non-disease entities (*e.g.*, low birth weight, suicide, violence . . .)." D.I. 327, Ex. 40 at P17 n.1.

[*82]

> n32 Further, Zoloth opines that "these symptom complexes are not only representative of distinct 'disease entities,' but are reportable on OSHA 200 logs, and are compensable under the Workers Compensation statutes of many states." D.I. 327, Ex. 40 at P17 n.2.

Punnett further defends the aforementioned studies and her conclusions in a supplemental report dated July 31, 1995. D.I. 327, Ex. 42. Addressing those criticisms set forth by Trichopoulous, Punnett counters that IBM's epidemiologist area of expertise lies primarily in the study of cancer, a disease whose diagnosis, progression and treatment naturally lend themselves to a very different kind of epidemiological study than that associated with musculoskeletal disorders. To wit, as a consequence of the steady worsening of health of a patient afflicted with cancer, that patient is extremely likely to seek medical care, be diagnosed by objective medical tests, be recorded in cancer registries and ultimately have cancer listed as the cause or underlying cause of death on a death certificate. Thus, administrative databases are generally available [*83] to retrospectively and prospectively ascertain cancer cases and potentially link them to other databases offering information on various possible exposure types. In contrast, individuals suffering from musculoskeletal disorders "may or may not seek treatment at any particular point in the progression of the condition; they may experience prolonged periods of pain and impairment or alternating periods of recovery and recurrence (with or without treatment); and there are no uniform case reporting mechanisms at either the state or federal level in this or most other countries." D.I. 327, Ex. 42 Supp. Report at 1-3. Moreover, unlike with cancer, musculoskeletal disorders may enter "remission" in patients with reduced exposure to the stressors, such as resulting from ergonomic intervention in the workplace, with the added benefit of the prevention of future disorders. Id.

Under these circumstances, where routine databases are not available for case ascertainment of musculoskeletal disorders, epidemiologists generally rely upon alternative approaches for the identification of affected individuals, such as self-reported symptoms. According to Punnett,

> cases defined by symptoms [*84] alone and those defined by findings on physical examination show extremely similar associations with the force and repetition characteristics of subjects' jobs (Silverstein 1986, 1987). . . There is a strong correlation between the frequency of symptoms, for example, among a group of occupations, and the frequency of workers' compensation claims, and of work-related repetitive trauma disorders recorded by employers in those same occupations (eg., Fine 1986). Standardized questionnaire items have been proposed (eg., Kuorinka 1987, Levine 1993) and evaluated with respect to their validity, reproducibility and sensitivity to change; the international comparability of case definitions is increasing.

D.I. 327, Ex. 42 Supp. Report at 3.

In further response to Trichopoulous' criticism that an outcome definition is inherently vague and weak when derived from questionnaires, the epidemiologist also notes that the use of questionnaire items to determine case status is not unique to musculoskeletal disorder study; standardized questionnaires for the assessment of chronic pulmonary obstructive disease have been widely used by epidemiologists for a number of years. Id. at 3-4. [*85]

Punnett's Supplemental Report and recent *in limine* testimony also specifically address and refute Trichopoulous' assertions that: (1) the studies upon which she relied were not peer-reviewed; (2) there is insufficient experimental evidence that musculoskeletal disorders may develop as a consequence of repetitive motion, static muscle loading and/or awkward postures; (3) the potential for information bias is much greater in studies where exposure measures were derived from questionnaire data and (4) those studies where there were multiple ergonomic exposure dimensions to the risk of musculoskeletal disorders poorly or vaguely assessed those potentially confounding individual exposures Id. at 4-6.

With regard to the issue of peer review, Punnett testified at her *in limine* hearing that there are several different types of accepted peer review, which in and of itself is a "fluid" concept. There is "formal" peer review, where an article submitted to a scientific journal is distributed to "outside" reviewers (other than the journal's editor and unknown author) for comments. Another form of peer review consists of presentation of a study at a scientific conference or symposium, [*86] where it is subjected first to an abstract critique for sound methodology and subject matter relevance by the particular conference's organizers, then later critiqued and commented upon by the conference's audience. Yet another form of peer review consists of review and comments on an article by the editor of the journal to which the work is submitted. D.I. 350 at 56-58.

According to Punnett, of the twenty studies upon which she relied, all were peer-reviewed papers, with the exception of the three NIOSH health hazard evaluation reports, two of which have subsequently been published in peer review journals. However, Punnett maintains that NIOSH reports actually undergo both an internal and (often) external peer review process prior to publication in their present state, so the NIOSH articles considered were also subject to the appropriate review. Further, in reference to her own report prepared for this litigation, Punnett notes that it was presented at a medical conference sponsored by the National Institute of Arthritis and Musculoskeletal Disease in conjunction with several other professional associations, and was reviewed by one of the editors who compiled the conference proceedings [*87] for publication. Moreover, it is currently under formal peer review for publication in an unidentified scientific journal. D.I. 350 at 90-92.

As for Trichopoulous' concerns that no study cited had examined individuals with clearly defined disease or an *a priori* determined clinical syndrome, Punnett replies:

> It may be true that in some studies these case definitions are based on symptoms "that are difficult to combine into a single disease from the point of view of clinical medicine." However, it is also the opinion of numerous physicians that clinical medicine does not yet provide the necessary diagnostic techniques for these conditions, especially in their early stages, or offer the appropriate taxonomy. The argument that an epidemiologist should only study clinically defined diseases begs precisely the contribution that epidemiology can make to the development of an appropriate clinical case definition and seems dated in light of many recent developments in the field. For example, epidemiologists were involved early in the scientific attempts to understand the immune system disturbance that is now characterized as Acquired Immune Deficiency Syndrome, but which was under [*88] study long before the disease mechanism was understood or a case definition had been standardized (utilizing epidemiologic data). Many epidemiologic studies utilize as their outcomes not clinically diagnosed disease but markers for early stages in pathogenesis . . . precisely because they offer a greater possibility of identifying affected individuals before clinical disease has developed and when secondary prevention will likely be more effective.

D.I. 327, Ex. 42 Supp. Report at 4 (citations omitted).

Thus, in summary, Punnett concludes:

> . . . there is epidemiologic evidence not only that "excessive functioning . . ." (and specifically) "VDT related work may in-

> deed generate musculoskeletal symptoms." (Ex. A, p. 13). There is also evidence that VDT usage is associated with disorders that produce findings on physical examination and clinical testing. Furthermore, there is evidence that musculoskeletal symptoms are valid and reproducible and serve as markers for medical care utilization and other endpoints, whether or not the pathology has been defined or can be objectively assessed as of yet with available clinical techniques. To my knowledge, there are no data [*89] showing the plausibility of alternative explanations for the associations between VDT use and upper extremity disorders. In the light of laboratory studies demonstrating several biologically plausible pathomechanisms, the epidemiologic evidence is most credibly interpreted as causal.

D.I. 327, Ex. 42 Supp. Report at 6.

In light of defendant's criticisms and plaintiffs' responses, the issue regarding the admissibility of Punnett's expert testimony is quite clear: the Court must determine whether Dr. Punnett had good grounds to rely on the studies in question to draw the conclusion that VDT use causes musculoskeletal disorders. See *Paoli II, 35 F.3d at 749;* See also *DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 953 (3rd Cir. 1990)* ("[HN21] Rule 703 is satisfied once there is a showing that an expert's testimony is based on the type of data a reasonable expert in the field would use in rendering an opinion on the subject at issue.").

The Third Circuit has stated that "[HN22] it is the judge who makes the determination of reasonable reliance, and that for the judge to make the factual determination under Rule 104(a) that an expert is basing his or her opinion on a type [*90] of data reasonably relied upon by experts, the judge must conduct an independent evaluation into reasonableness." *35 F.3d at 748.* Of course, "the judge can . . . take into account the particular expert's opinion that experts reasonably rely on that type data, as well as the opinions of other experts as to its reliability, but the judge can also take into account other factors he or she deems relevant." Id.

While the parties have presented undeniably conflicting testimony regarding Punnett's examined studies and her resulting conclusions, the Court finds that the studies relied upon by Punnett are of the type reasonably relied on by experts in the field to render a conclusion with respect to general causation. Although none of the underlying studies actually concludes that VDT use causes musculoskeletal disorders, it is also recognized that "[HN23] epidemiology cannot prove causation; causation is a judgment issue for epidemiologists and others interpreting the epidemiological data." Schneck Op. at 31, quoting the *Federal Judicial Center, Reference Manual on Scientific Evidence* 157 (1994); see id. at 126 ("Association is not *causation* . . . . A strong association that [*91] is demonstrated consistently in a series of research projects leads a researcher to infer that a causal relationship exists. Even the best of studies do not demonstrate more than a high probability of causal relationship between exposure to an agent and a disease."); see also *Diaz v. Johnson Matthey, Inc., 893 F. Supp. 358, 375 (D.N.J. 1995)* (citations omitted) ("A cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. . . . If conclusive evidence were necessary to admit . . . [a] theory on general causation, we might as well be proceeding under the Frye general acceptance test rejected by Daubert."). As noted in Schneck, Zoloth strongly approved of Punnett's conclusion on general causation in light of her proper reliance upon underlying studies which were both reliable and of the type that an expert would reasonably rely on to establish causation. D.I. 327, Ex. 40 at P18. While IBM's expert, Trichopoulous, disputes these conclusions, this Court finds sufficient evidence to hold that Punnett had "good grounds" to rely on these studies to reach her [*92] conclusion, and that Trichopoulous' contrary testimony is more properly reserved for consideration by a jury as to the issue of weight. Consequently, it is recommended that defendant's motion to exclude Punnett's general causation testimony be denied.

As part of its argument, defendant contends that since Dr. Punnett does not relate the injuries allegedly suffered by plaintiffs to any amount of typing or keyboard use, her opinion testimony "does not fit the allegations of the plaintiffs in this case, and is, therefore, completely unhelpful to the trier of fact," relying on Daubert at 2795-96. [HN24] The Daubert analysis under the "fit" or helpfulness requirement of Rule 702 necessitates "a valid scientific connection to the pertinent *inquiry* as a prerequisite for admissibility." Id. (emphasis added). As noted by Daubert, "'Fit' is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." Id. However, Punnett's general causation opinion is not being propounded in the abstract and is not the only opinion on causation. Although Punnett is not being called upon to testify about a relationship between [*93] plaintiffs' alleged injuries and their keyboard use or the IBM keyboards involved, as will be addressed further herein, Dr. Bleeker specifically relies upon Dr. Punnett's methodology and analysis in formulating her general causation

opinion and applies that to the injuries involved in this matter. Therefore, defendant has failed to demonstrate that Punnett's testimony will not "assist the trier of fact to understand the evidence or to determine a fact in issue." *Fed. R. Evid. 702*.

C. Dr. Margit Bleeker

Margit Bleeker ("Bleeker"), M.D., is a board-certified psychiatrist and neurologist who serves as the Director of the Center for Occupational and Environmental Neurology in Baltimore, Maryland and as a consulting neurologist to the Hopkins Health System. D.I. 310, Curriculum Vitae, p. 2. She is also a medical/ergonomic consultant at the Washington Post, for which she reviews workstations and evaluates employees who are developing repetitive strain injuries. D.I. 310, Ex. A-5 at 20-21. Plaintiffs proffer the opinions of Bleeker on the issue of medical causation generally, and specifically with respect to plaintiffs' individual claims of carpal tunnel syndrome resulting from use [*94] of keyboards. n33 D.I. 310, Ex. A-3 at 8-9.

> n33 In her deposition, Bleeker outlined the issues she would address in her expert testimony, including causation and warnings. According to the doctor, her opinions do not center upon a particular keyboard, such as the IBM keyboard design now at issue, but are more generalized. D.I. 310, Ex. A-3 at 10.

With regard to the issue of general medical causation, Bleeker opines that "*carpal tunnel syndrome, as far as I'm concerned, is a keyboard issue* and I include with the keyboard-- I include, for instance, the height of a keyboard tray even though somebody might say that's the workstation. That is where the keyboard is being used and that is part of the keyboard problem. I mean, the height of the monitor, whether that's inappropriate, has nothing to do with carpal tunnel syndrome." D.I. 310, Ex. A-73 at 299 (emphasis added). Bleeker's summary statement proffered herein followed detailed deposition responses regarding keyboard design and use (specifically, typing technique, [*95] position, posture, intensity, duration and key depression force) and their association with such repetitive strain injuries as CTS. n34 D.I. 310, Ex. A-69-71 at 276-286, A-73 at 291-296. During her recent *in limine* testimony in this matter, Bleeker maintained that consistent keyboard use may cause carpal tunnel syndrome. (See Bleeker *In Limine* Hearing Testimony, Nov. 3, 1996 and Dec. 6, 1996, D.I. 363 and 353 respectively).

> n34 Bleeker admittedly lacks expertise in keyboard design and required and appropriate warnings. D.I. 310, Ex. A-92 at 295, Ex. A-73 at 297-99. Nor is she being offered as an expert to testify in those areas. D.I. 322 at 25.

As to the issue of specific causation, in a January 5, 1996 occupational neurology evaluation of Allen, Bleeker records that "Ms. Allen is a 32-year-old right-handed female who was originally evaluated on November 3, 1994, for continuing problems in both of her hands following carpal tunnel release bilaterally. At that evaluation, the history and physical examination [*96] were suggestive of carpal tunnel syndrome bilaterally." D.I. 310, Ex. A-111. As stated as her "Impression" during the November 1994 examination, the doctor again concludes that "the history demonstrated a strong temporal association between the onset of symptoms and increased keyboard use." D.I. 310, Ex. A-111. While Bleeker's November 3, 1994 and January 5, 1996 occupational neurology evaluations of plaintiff Bowers do not explicitly cite keyboard use as the cause of her carpal tunnel syndrome, both reports focus on Bowers' keyboard activities and its alluded direct association with her CTS injury and its recurrence. D.I. 310, Ex. A-113-17. Moreover, in her deposition testimony, Bleeker unequivocally claims keyboard use as the cause of both plaintiffs' medical problems:

> Q: Is it your opinion that Mrs. Allen's and Mrs. Bowers' carpal tunnel syndromes were caused solely by their use of computer keyboards?
>
> A: What you have to realize is that when you are formulating that opinion is that you look at the fact that these individuals -- I could not find any other stressor except a change in what had gone on in their work place or the fact that they were using their keyboard [*97] in, maybe, a poorly designed work place and they weren't using the keyboard correctly. That caused the problem.

D.I. 310, Ex. A-73 at 298.

During her *in limine* hearing in November and December 1996, Bleeker was equally emphatic that plaintiffs' respective CTS problems were a result of computer keyboard use, rather than of their routine activities and hobbies, although she later conceded that the activities of daily living (ADLs) and other modifiers (i.e., body

weight, birth control pills) could exacerbate the CTS conditions:

> Q: The question basically was, did you come to a determination of causality [of CTS] through these examinations of her [Ms. Bowers'] problems?
>
> A: Yeah. I think it's - by causality, I'm more interested in *when the problem began, and what was going on at that point.* And I feel that it was due to using the keyboard. And, unfortunately, in this case, it looks like it was exacerbated because the keyboard, by the patient's description *when she was demonstrating how she was using it, was clearly too high.*

D.I. 363 at 25.

* * *

> Q: Do you state anywhere, in your impression, that the etiology of Ms. Bowers' diagnosed [*98] bilateral carpal tunnel syndrome is due to the keyboard or any aspect of the keyboard?
>
> A: I think if you read the entire impression, what I am trying to do is to demonstrate that, for instance, when her condition was treated, the bilateral carpal tunnel syndrome was treated with surgery, symptoms improved. She had successful surgical outcome. And then, when she returned back to work, the symptoms again increased in severity.
>
> I make statements like that because, again, it is having the relationship between the development of the symptoms with the use of the keyboard which is helping us to establish causality.
>
> I tried to explain what was going on with the elevated keyboard, and indicating that she was typing in a position that where she could have increased pressure inside the carpal canal. Again, a causal relationship between increased pressure in the carpal canal, we know that from the literature, that people with carpal tunnel syndrome have increased pressure within the carpal canal, and that is clearly a risk factor for the development of carpal tunnel syndrome. So, yes, as far as I am concerned, there is not a question that the use of the keyboard was causally associated [*99] with the development of the carpal tunnel syndrome.

D.I. 353 at 12-13.

* * *

> Q: What sort of non-work activities did you note in Ms. Bowers' history that could be possible causes of carpal tunnel syndrome?
>
> A: I think that you need to realize that there are many contributing factors to the development of carpal tunnel syndrome. Could her employment at the Acme, where she is grabbing parcels and putting them through the scanner, could that have added a little notch. Obviously, it could. But the fact is that you need to look at the number of hours. It's just the same explanation that is given, oh, it's the crocheting, it is the knitting, it is washing the clothes at home. You are not doing that for 37 and a half hours a week. You can actually do a little bit and stop. That is very different than with many of these jobs on the keyboard.

D.I. 353 at 22.

* * *

> Q: You did not say or conclude in this report, did you, that keyboard use caused her [Ms. Allen's] carpal tunnel syndrome.
>
> A: Well, I guess I said it in my way. If by saying there a strong temporal association between onset of symptoms and a dramatic increase in her keyboard use, to me, [*100] that says that one caused the other.
>
> Q: Is that enough, Doctor, just having a temporal association between two things, is that enough to assume causation?
>
> A: Clinically? Sure.

Q: From a scientific and medical perspective, doesn't causation require more than just a temporal relationship between the suspected cause and the suspected effect?

A: No. I mean, its very much -- if somebody is throwing a baseball and develops shoulder pain, are they able to associate throwing the baseball with the onset of the shoulder pain? I mean, I don't think too many people would question that. And that's the same thing we're talking about here.

Q: How about in an area of controversy; that is, where it's controversial in the scientific and medical arena as to whether a given cause produces a given effect. In that situation, is a temporal relationship alone sufficient to premise or basis an opinion of causation between the two items?

A: You know, what it is, is I don't know if I fully agree with -- we have been discussing causation of carpal tunnel syndrome with keyboard use. You have brought up that it's a multifactorial problem. No one is going to deny that it's multifactorial. [*101] One of the major factors happens to be ergonomic stressor from the keyboard. If you want to bring in, you know, other modifiers, such as her weight, whether she's on birth control pills, other things like that, those are modifiers.

D.I. 353 at 122-23.

* * *

Q: Is it your impression that her [Ms. Allen's] use of the switchboard [versus the computer keyboard] and her activities of daily living were the cause of her symptoms?

A: Absolutely not.

D.I. 353 at 130.

During her *in limine* testimony on November 23, 1996, Dr. Bleeker described the typical methodology applied in making a diagnosis of an illness, and whether there is a causal factor associated with the patient's particular occupation:

Basically, one approaches as one approaches any patient with reviewing any medical records that have been provided by the individual or their [sic] physician. One gets a history. And part of that history is specialized, because part of it is an occupational history, where one is going through the various jobs and positions that the person has been in, and what those positions have actually entailed.

And one also obviously goes through the medical [*102] history; meaning, what other medical conditions have they been diagnosed with. Do they have any other sort of general symptoms that might suggest that there's an underlying condition that hasn't been diagnosed that needs to be -- that needs to be looked at.

And then one does a physical examination. If it's indicated, nerve conduction studies are performed. In some cases, we actually even do MRIs [magnetic resonance imaging] as part of our workup, because we may be seeing somebody after surgery who is having problems.

Again, there are different avenues that one may take in the evaluation. And as part of this history taking and examination, one is trying to exclude other etiologies. So one is looking at hobbies and other ergonomic stressors to the upper extremities.

And one is always being very careful to try and determine the temporal association between what happened in the workplace and the onset of the symptoms. And what actually went on with relieving the symptoms, if they were treated by another physician, you know, what was modified.

D.I. 363 at 8-10.

Bleeker further opined that when examining the impact of nonwork activities on the development of [*103] CTS, one typically considers the intensity and duration of each nonwork activity.

When questioned about the basis for her temporal association between CTS and keyboard use (i.e., additional reliance on literature on occupational problems or primary emphasis on her own clinical experience), Bleeker responded:

> The thing is that one obviously keeps abreast of the literature. I mean, I have a library with many journals, which one can see which ones we have been subscribing to.
>
> So one is -- carpal tunnel has been something that's been of interest to me, since I started in the early 80s. So it is something that whatever journal I'm looking at, and if it has a carpal tunnel article, it's always pulled and put into my files.
>
> So one is relating to a body of literature that has been relating ergonomic stressors and these various health outcomes. I certainly can't necessarily point to one paper and say, this was "the article," because it's basically many articles which have shown similar outcomes that I'm not [sic] relying on.

D.I. 363 at 10-11.

Bleeker further commented on Punnett's work which reviewed health outcomes related to keyboard use, n35 stating that [*104] where CTS is a frequent outcome in the papers, there is a demonstrated consistency between exposure and such outcome which may be used to establish causality.

> n35 Bleeker suggested that the work of Punnett's to which she was referring may have been in a chapter of the Journal of Hand Surgery, but also noted that she had heard Dr. Punnett present the data at a meeting in San Francisco. Further discourse between Bleeker and defense counsel indicates that the Punnett work in question is the same material published from the proceedings of the 1994 Bethesda, Maryland meeting of the American Orthopedic Surgeons, which is the basis of Dr. Punnett's testimony in this case (the Punnett Report).

With regard to the issue of general causation, defendant IBM's primary argument is that Bleeker's conclusion of a causative relationship between the use of keyboards and the development of such musculoskeletal injuries (i.e., carpal tunnel syndrome) as those suffered by plaintiffs is unsupported by recognized, scientifically verifiable [*105] studies. Moreover, assuming that legitimate scientific studies relate CTS to typing, there remain many other factors contributing to and causing CTS. D.I. 309 at 20-22, D.I. 334 at 13-14.

(a) General Causation

(1) Daubert/Paoli II Factors

(i) Does the Methodology Consist of a Testable Hypothesis?

Defendant does not contend that Dr. Bleeker's hypothesis -- that repeated keyboard use is a substantial factor in the development of a cumulative musculoskeletal disorder such as carpal tunnel syndrome, and that such a disorder can be prevented and treated with early identification and ergonomic work modifications -- is not testable. Accordingly, this factor will weigh in favor of the admissibility of the proffered testimony.

(ii) Has the Methodology Been Subject to Peer Review?

During her recent *in limine* testimony Dr. Bleeker specifically referred to the review of epidemiologic studies relating health outcomes (such as CTS) to reported keyboard use presented by Dr. Laura Punnett and previously described and considered at length by this Court. Bleeker cited Punnett's Report, among other more broad references to available scientific literature, as a basis for her [*106] general causation opinion proffered in this litigation. n36 D.I. 363 at 48-50. This Court has already determined that Punnett had good grounds for relying on the studies she used in formulating her general causation conclusion, and that the conflicting opinions of the respective parties' outside experts on the reliability of such studies is appropriately left to the jury to weigh.

> n36 There is no doubt that this Court would have preferred a broader base of specifically cited literature and a more defined, delineated methodology with regard to general causation. And, indeed, Bleeker's *in limine* hearing testimony suggests that she reaches her conclusions upon consideration of numerous scientific articles, upon which, unfortunately, counsel for either party failed to elicit elaboration. However, that notwithstanding, Bleeker's primary reliance on Punnett's Report is sufficient for the conduct of a Daubert/Paoli II analysis to determine the admissibility of her expert testimony.

With regard to issue of specific [*107] causation, according to the Journal of American Medical Association ("JAMA") report of Dr. David Rempel ("Rempel"), a well-regarded expert, the following mainstream methodology is appropriate for application to ascribe the cause of occupationally-related upper extremity cumulative trauma disorders: (1) make a reasonably specific and accurate diagnosis; (2) exclude nonoccupational explanations for the disorder; (3) determine whether the disorder is plausibly associated with work-related risk factors, based upon the patient's work history; (4) interview the patient to find out whether the risk factors are present in sufficient degree; and (5) determine whether a temporal association exists between the work place risk factors and the onset or aggravation. D.I. 329, Ex. 54 at 839.

Applying Rempel's outlined methodology, Dr. Bleeker conducted physical examinations of the plaintiffs, took their occupational, social and medical histories, n37 reviewed their medical records and conducted the conventional clinical tests and measures appropriate to the diagnosis (such as Phalen's, Finkelstein, Tinel's, nerve conduction studies and MRI of the affected extremities). Upon evaluation of the aforementioned [*108] factors, including the reasoned exclusion of nonoccupational factors -- "potential confounders" or factors other than keyboard use which may have contributed to plaintiffs' CTS -- Bleeker opined that plaintiffs' occupational use of keyboard equipment "was the cause of the development of [their] carpal tunnel syndrome." D.I. 311, Ex. A at 65. While the Court acknowledges that Dr. Bleeker did not account for every single possible potential confounder, it nonetheless recognizes the reliability of her conclusions.

> n37 Plaintiffs maintain that having eliciting their social and occupational histories, Bleeker was thus fully aware of both the nature and extent of plaintiffs' exposure to defendant's products, and of any other factors which might be medically relevant to a determination of causation in their cases. D.I. 322.

In sum, this Court finds that the respective methodologies in question for general and specific causation have been subject to peer review and this consideration favors the admission of the proffered [*109] testimony.

(iii) Is There a Known or Potential Rate of Error?

The rate of error in Dr. Bleeker's methodology is directly related to the rate of error of those studies upon which her general causation conclusion rests -- i.e., such as the reported results of Dr. Laura Punnett's review of the relevant literature on health outcome and keyboard use. With respect to Dr. Bleeker's consideration of Dr. Punnett's Report, as well as the studies relied upon by Dr. Punnett, this Court has already determined that there were good grounds for relying on such works. Ergo, the rate of error in these studies cannot be so significant thereby rendering invalid a conclusion with respect to general causation. However, the known or potential rate of error with respect to any of the other studies to which Dr. Bleeker broadly referred and relied upon in reaching her conclusion has not been posited. As such, this factor balances only slightly in favor of the admission of the proffered testimony.

(iv) Were There Standards Controlling the Technique's Operation?

Dr. Bleeker's underlying methodology regarding general causation relies substantially upon that utilized in Dr. Punnett's Report. And as [*110] previously noted, the Court has already determined that there were good grounds for relying upon the Report and the validity of the studies contained therein. As such, this component will weigh in favor of the proffered testimony.

(v) Is the Methodology Generally Accepted?

As the Court has noted in its analysis of previous factors, Dr. Bleeker's methodology applied in reaching her conclusion is substantially dependent upon the validity of that of Dr. Punnett's utilized in reaching her Report results, for each individual factor of the Daubert/Paoli II analysis. And as under the other factors, the Court holds that the methodology at issue is a standard and generally accepted epidemiological methodology. Thus, this element favors the admission of the proffered testimony.

(vi) Is There a Relationship Between the Technique and Other Methods Established to be Reliable?

The Court's previous comments address this factor. While a broader base of literature and a more defined, delineated methodology with regard to general causation would have been preferred, Bleeker's primary reliance on Punnett's Report nonetheless supports that the doctor's methodology closely resembles established [*111] and reliable methods. Accordingly, this factor will weigh in favor of the admission of her testimony.

(vii) Are the Qualifications of the Expert Based Upon the Methodology Appropriate?

Defendant does not challenge Dr. Bleeker's qualifications for proffering a general causation opinion. With regard to specific causation, however, defendant points out that Bleeker is not a medical expert on hand disorders. While this may indeed be true, the Court is persuaded that Bleeker's medical training and extensive experience in the medical area now in issue render her qualified to speak on the matter of specific causation in

this case. This factor therefore weighs in favor of the admissibility of the proffered testimony.

(viii) Non-Judicial Uses

The Court's prior criticism that Dr. Bleeker was a certain degree vague with regard to specifically identifying the scientific literature upon which she based her general causation conclusion, with the marked exception of Dr. Punnett's study, still stands. However, there is no doubt that the methodology utilized by Dr. Punnett, and adopted by Dr. Bleeker, has been used on a regular basis in non-judicial settings within the field of epidemiology. [*112] The same routine use certainly holds true with regard to the methodology applied by Dr. Bleeker in her specific causation determination. Thus, this factor will also weigh in favor of the proffered testimony.

(x) Conclusion

Upon consideration of the aforementioned factors, this Court finds that the Daubert/Paoli II analysis weighs in favor of admitting Dr. Bleeker's proffered testimony on general causation.

(2) Fit

Fed. R. Evid. 702's third requirement -- that the evidence is relevant or "fits" under the facts of the case -- also must be satisfied before an expert's proffered testimony may meet the Daubert test.

In the case at bar, Dr. Bleeker's testimony has been offered for the proposition that repeated keyboard use can cause such musculoskeletal disorders as carpal tunnel syndrome. In support of this assertion, Bleeker relies substantially upon the Punnett Report of epidemiological studies on this subject matter. Accordingly, this Court finds that [HN25] Bleeker's testimony regarding general causation is admissible, where there is a "connection between the scientific research or test result to be presented, and particular disputed factual issues in this case." *Velasquez,* [*113] *64 F.3d at 850* (quoting *Downing, 753 F.2d at 1237).*

(3) Conclusion

Based on the foregoing analysis, the Court recommends that Dr. Bleeker's testimony on general causation be admitted.

(b) Specific Causation

With regard to the issue of specific causation, IBM states that Bleeker's opinion that plaintiffs must have developed CTS from typing because of the "temporal" relationship between the use of keyboards and the development of such injuries. derived from the history given by plaintiffs themselves -- is neither supported by the facts of this case nor by recognized scientific studies. D.I. 334 at 14. In particular, defendant asserts the following criticisms regarding Bleeker's qualifications and the formation of her causation conclusions: (1) Bleeker's explanation of the relationship of the physiology of plaintiffs' CTS to the use of a computer keyboard and why CTS must have been caused by plaintiffs' typing is not credible, where she is unable to cite to one scientifically verifiable study which supports her conclusions, nor can she state that her proffered explanation applies in fact to plaintiffs; (2) further, Bleeker is not a hand surgeon, and contradictory reports [*114] by plaintiffs' own hand surgeons, Drs. Boulos and Raisis, indicate that (i) no studies (to Raisis' knowledge) relate CTS to typing, (ii) there are many other factors which contribute to and cause CTS, including "activities of daily living," and (iii) even if typing is one of the causes of CTS, the amount of typing and posture at a keyboard would not correlate directly to the development of CTS; (3) the doctor never questioned the plaintiffs about their typing technique or examined the particular keyboards or workstations used by plaintiffs, nor does she now specifically address the IBM keyboards at issue; (4) Bleeker is able only to opine that there is a "temporal" relationship between plaintiffs' typing and their development of CTS, a degree of association which even plaintiffs' expert epidemiologist Punnett recognizes is insufficient to conclude the existence of a cause and effect relationship; and (5) Bleeker is unable to satisfactorily explain why plaintiffs continue to suffer from CTS symptoms even after CTS release surgery and the discontinuation or curtailment of their typing, eventually conceding that "activities of daily living" could be responsible for Bowers and Allen's [*115] current symptoms. D.I. 309 at 20-22, D.I. 334 at 13-14.

Defendant further argues that Bleeker's methodology is unreliable where her conclusions are based upon incomplete case histories of the plaintiffs. To wit, Bleeker was unaware that: (1) Allen had been in an automobile accident and had fallen and sprained her wrist; (2) Bowers also was involved in a car accident; n38 and (3) Bowers worked on other cash registers at Strawbridge's and J.C. Penneys, and, significantly, was using a cash register of unknown origin at Acme at the same time she was working on IBM machines. D.I. 334 at 14.

n38 In her *in limine* testimony, Bleeker commented that she had, in fact, noted during her first examination of Allen that the plaintiff had been involved in two motor vehicle accidents in 1989 and 1993, which predated the onset of her CTS symptoms and eliminated them as a cause. D.I. 353 at 19-21.

Plaintiffs maintain that Bleeker is eminently qualified to render expert testimony regarding specific causation and applied a reliable, [*116] medically-accepted methodology in her conduct of that analysis. D.I. 322 at 25-29. Specifically, Bleeker conducted physical examinations of the plaintiffs, took their occupational, social and medical histories, n39 reviewed their medical records, and conducted the conventional clinical tests and measures appropriate to the diagnosis (such as Phalen's, Finkelstein, Tinel's, nerve conduction studies and examined an MRI of the affected extremities). Only upon evaluation of the aforementioned factors, including the reasoned exclusion of nonoccupational factors -- "potential confounders" or contributing factors to the development of CTS unrelated to keyboard use -- did Bleeker opine that plaintiffs' occupational use of keyboard equipment caused their development of carpal tunnel syndrome. Id.

n39 As noted previously, plaintiffs maintain that having eliciting their social and occupational histories, Bleeker was thus fully aware of both the nature and extent of plaintiffs' exposure to defendant's products, and of any other factors which might be medically relevant to a determination of causation in their cases. D.I. 322.

[*117]

As for defendant's contention that plaintiffs' own hand surgeons Raisis and Boulos refute Bleeker's findings, plaintiffs characterize the charge as "advancing specious and deceptive claims." Specifically, plaintiffs note that neither surgeon offered any opinion or finding about the cause of plaintiffs' injuries. Rather, "responding to the entirely leading questions of defense counsel, Dr. Boulos prosaically and generally agreed that various factors, including typing activities, could 'contribute' to the development of carpal tunnel syndrome." In her analysis, Bleeker considered and eliminated any such "confounding factors." Moreover, plaintiffs maintain that, as a legal matter, the existence of other such contributing agents to plaintiffs' upper extremity injuries does not negate defendant's liability for its own misconduct to the extent thus was similarly a contributing factor. D.I. 322 at 28, n.13.

With respect to Raisis' comments that he was unaware of specific studies demonstrating the causal connection between typing and the development of CTS, plaintiffs emphasize Raisis' further remarks that it was his understanding that this connection was well accepted in "courses and personal [*118] communications with other physicians." n40 Finally, even if defendant is accurate in his assertion that these physicians actually support IBM's contentions on the issue, the conflicting testimony in no way supports exclusion of Bleeker's testimony under a Daubert admissibility motion. D.I. 322 at 28-229, n.13.

n40 With regard to this issue of "general" causation, Bleeker also stated in deposition testimony that the causal link between keyboard use and CTS is "clearly accepted" among medical professionals in the area of occupational medicine. D.I. 330, Ex. 65 at 85-87. The doctor further addressed the role of keyboard design, stating that "keyboard designs . . . have adversely affected the health of . . . users" (Id. at 276), with specific criticism directed at such design factors as (1) "the amount of force that is required to depress" the keys (Id. at 276); (2) "how the keyboard is actually angled," placing the hands in "ulnar deviation" (Id. at 277); (3) the overloading of tasks on a single hand (Id. at 276); and (4) the lack of instructions regarding "how one is to use the keyboard." Id. at 277.

[*119]

Defendant's argument that Bleeker fails to explain why plaintiffs continue to experience symptoms of CTS even after surgery is likewise unfounded, according to plaintiffs. Bleeker's deposition testimony explained that, with respect to Allen, "as the healing process goes on, . . . the canal . . . is not allowing her to have enough space in there," D.I. 330, Ex. 65 at 167, 174, and "the way the transverse carpal ligament healed following surgery, that might have made . . . the canal slightly smaller." Id. at 317. Accordingly, Bleeker concluded that "the only reason she is continuing to suffer carpal tunnel syndrome is because of the original typing." Id. at 324. The doctor further noted that Allen "returned to typing four weeks after surgery and Mrs. Bowers did not return to work until a year after surgery." Id. at 190. As for Bowers' continuing symptomatology, Bleeker commented that "she did have improvement of her symptoms following surgery," but that there was cause for concern that "she was returning to the same job with no ergonomic modifications." Id. at 212-213. The doctor also stated that "one possibility which we do see is re-entrapment of scar tissue only because [*120] [Bowers] did have good relief of her symptoms when the pressure was relieved immediately following surgery" (Id. at 214), but following the surgery "we have a closed canal again and you are just now returning that person back to the same job which produced the condition initially, [creating] a very high chance of the individual developing the problem again." Id. at 352.

Plaintiffs' position is of merit. The Third Circuit has found that "[HN26] most of the Daubert factors -- testability, general acceptance, peer review, and degree of production of errors, are of only limited help in assessing whether the methodology [of a physician] is reliable (i.e., scientifically valid)." *Paoli II, 35 F.3d at 758.* Instead, courts must consider whether:

> either (1) [the doctor] engaged in very few standard diagnostic techniques by which doctors normally rule out alternative causes and the doctor offered no good explanation as to why his or her conclusion remained reliable, or (2) the defendants pointed to some likely cause of the plaintiff's illness other than the defendants' actions and [the doctor] offered no reasonable explanation as to why he or she still believes that [*121] the defendants' actions were a substantial factor in bringing about that illness.

Id. at 760.

In the case at bar, while the Court finds that although Dr. Bleeker did not eliminate every single conceivable confounding factor, her opinion was nonetheless based upon a sufficient number of diagnostic techniques to be deemed reliable. To wit, prior to rendering her opinion on each plaintiff, Dr. Bleeker: (1) conducted physical examinations of the plaintiffs; (2) recorded their medical histories and reviewed their medical records; (3) conducted the conventional clinical tests and measures appropriate to the diagnosis (such as Phalen's, Finkelstein, Tinel's, nerve conduction studies and review of magnetic resonance imaging of the affected extremities); (4) took their occupational and social histories; and (5) considered alternative causes. D.I. 363 at 11-26. Moreover, as plaintiffs correctly note, the Doctor did address the issue of why plaintiffs continue to experience CTS symptoms. Her testimony confirms that the use of the keyboard was a factor in the recurrence of the CTS symptoms.

As for defendant's alternative criticisms regarding other physicians' opinions about the causation [*122] of plaintiffs' CTS problems, specifically, the general association (or lack thereof) between CTS and keyboard use and other contributing factors, this Court finds that any such analyses go to the weight to which the testimony is entitled. Accordingly, this Court recommends defendant's motion *in limine* to exclude the specific causation testimony of Dr. Margit Bleeker be denied.

D. Dr. Robert Cunitz

Dr. Cunitz ("Cunitz") is a human factors psychologist "specializing in the area of the safety of the interaction of people with products as they are used in the real world." D.I. 310, Ex. A-161. In other words, he is a "warnings" expert. According to Cunitz's report on warning requirements for keyboard and computer use, specifically prepared for this litigation, "warnings of the danger of various musculo-skeletal injuries were necessary so that equipment purchasers, employers, supervisors and users could become alerted to and knowledgeable with respect to the range of known and suspected risks associated with intensive keyboard use." D.I. 310, Ex. A-164. Furthermore, "the keyboard and data entry products involved in this litigation were defective in the absence of the necessary [*123] warnings . . . . [and] the products involved were unreasonably dangerous because of the defects described above which could have and should have been corrected." D.I. 310, Ex. A-164.

Plaintiffs assert that Cunitz satisfies the criteria to proffer expert testimony, as demonstrated by his professional credentials, "fully informed and reliable methodology," and past acceptance by other courts as a "warnings" expert qualified to testify on the subject. D.I. 322 at 23-24. Defendant maintains that Cunitz's testimony should be excluded where Cunitz: (1) is not qualified to testify about the alleged causal relationship between typing on any keyboard and the development of physical injuries such as CTS; (2) fails to identify any alleged defect in the design of the keyboards used by plaintiffs; and (3) is unable to state with any specificity that a particular warning would have prevented the alleged injuries suffered by plaintiffs, instead basing his conclusions on "unsupported speculation." D.I. 309 at 20-25.

[HN27] In its determination of whether a witness may be considered as an expert, this Court must compare the "area in which the witness has superior knowledge, skill, experience, or education [*124] with the subject matter of the witness's testimony." *Carroll v. Otis Elevator Co., 896 F.2d 210, 212 (7th Cir. 1990)* (quoting *Gladhill v. General Motors Corp., 743 F.2d 1049, 1052 (4th Cir. 1984)).* Moreover, while an "expert may give his opinion on a particular matter within the scope of his expertise, that opinion must be based on facts." *Randolph v. Laeisz, 896 F.2d 964, 967-68 (5th Cir. 1990).*

Characterizing his "assignment" from plaintiffs as an analysis "of a general nature without emphasis on any one manufacturer or supplier or any particular claimant," and his report as "applicable to all computer and data entry keyboard situations," Cunitz opines that appropriate warnings would have reduced or eliminated the dangers of musculoskeletal injuries experienced by keyboard users. D.I. 310, Ex. A-163-65. The psychologist further

states that responsibility for provision of such warnings lay with the manufacturers and suppliers of the computer equipment, and that keyboard and data entry products were defective and unreasonably dangerous instruments absent the cautionary notice. D.I. 310, Ex. A-164.

During his *in limine* testimony, Cunitz outlined the traditional methodology [*125] applied by human factors specialists when conducting a risk/safety analysis on a man-machine interface. According to Cunitz, the first step, a task analysis, focuses on understanding how a person interacts with a given product. Cunitz *In Limine* Hearing, D.I. 349 at 7. Specifically, a task analysis identifies the product and its essential features, as well as the process of how the person interacts and deals with the product. Thereafter, examination of the associated safety component is conducted through such hindsight techniques as surveying the product's prior incident, injury, accident and complaint information. D.I. 349 at 7. Additionally, foresight techniques such as failure mode, effect analyses and faulty analyses applied by systems safety professionals on the product are considered. D.I. 349 at 8.

Cunitz also stated that a common concern for human factors specialists is the issue of warnings, resulting from hazard, risk and danger analyses where the hazardous ("harmful") features of a product are identified, as well as the manner in which people may be exposed to those hazards. D.I. 349 at 8. The goal is to determine the risk and type of injury possible from a person's [*126] foreseeable use of a particular product, and the intervention (i.e., warnings and/or instructions) required to avoid such harm. Where a human factors specialist is not an expert in all areas of harm, the appropriate expert would be consulted to assist in the aforementioned analysis. For example, if the product at issue is of a toxological nature, Cunitz would consult with a toxologist. D.I. 349 at 8-9. With respect to the general issue of warnings and the conduct of a risk/safety analysis, there are a number of long-accepted reference articles from authoritative sources, such as the National Association of Manufacturers, the National Safety Council, the American Psychological Association and the American National Standards Institute. D.I. 349 at 10-12.

The provision of warnings serves three distinct purposes. The first purpose involves the notion of "informed consent;" that a warning allows a person to *knowingly* assume or avoid a risk. D.I. 349 at 16. The second purpose for warnings is as a safety device or behavioral guard. D.I. 349 at 16-17. Finally, warnings serve as reminders to people that they are about to encounter a dangerous situation. D.I. 349 at 17. While all warnings [*127] share a common thread, they are naturally adapted for effective communication to the population at issue, which may require consideration of cultural differences. During an assessment of whether a warning was merited in the instance of an individual's injury from product use, i.e., as during a forensic investigation, a human factors specialist generally does not directly interview the injured party, instead usually relying on the party's sworn deposition testimony or the like. D.I. 349 at 23. Such an approach is practiced because human factors specialists do not have substantial interview training and skills, and also because it is especially difficult to establish how a specific person who has changed as a result of his injury might have previously acted in response to a particular situation. D.I. 349 at 12. Rather, predictions are more readily available for what groups of individuals in similar circumstances are likely to do in response to warnings. As such, Cunitz testified that a direct interview is highly unlikely to elicit any significant information not already provided through sworn deposition testimony. D.I. 349 at 24-25.

With regard to the case at bar, Cunitz conducted a [*128] general human factors task analysis to assess the need for and adequacy of warnings with respect to musculoskeletal injuries associated with the use of the computer and other data entry keyboards. To this end, he considered the nature of the equipment and the keyboard tasks involved; however, he did not examine the actual workstations. Nor did he consult with outside experts or examine the plaintiffs' respective deposition testimony. Instead, Cunitz relied on testimony from the plaintiffs' medical and ergonomic experts, although he noted that he also was provided with a substantial amount of research information in the medical and ergonomics literature. D.I. 349 at 30-34.

Significantly, while generally familiar with the notion of an association between musculoskeletal injuries and keyboard use, Cunitz freely admits that his general conclusions regarding the unspecified computer keyboards, musculoskeletal disorders and the necessity of warnings n41 are premised upon a series of assumptions, whose validation presumably would be provided by plaintiffs' other expert witnesses. D.I. 310, Ex. A-162. Cunitz's assumptions include, but are not limited to, that:

> . . . the danger [of [*129] musculoskeletal injuries from keyboard use] can be reduced or eliminated if one or more of the following interventions are accomplished: (a) early identification and recognition of symptoms, (b) appropriate medical treatment, (c) changes to furniture, (d) modification of keyboard and monitor placement, (e) the use of rest breaks, exercise breaks, and other means to interrupt the continuous flow of the work, and (f) train-

> ing in keyboarding techniques such as hand, wrist and arm position and maintenance of proper posture.

D.I. 349 at 57.

> * * *
>
> . . . that the claimants involved in the litigation will have been diagnosed as having musculoskeletal injuries associated with computer and data entry equipment.

D.I. 310, Ex. A-162-63.

> n41 In his assessment of whether warnings were merited, Cunitz applied a "reasonable suspicion of harm standard," which, while his own wording, was argued by the human factors psychologist as being entirely consistent with the threshold standard widely accepted in the human factors field. D.I. 349 at 38.

[*130]

Defendant's position regarding Cunitz's testimony is compelling. While Bleeker, plaintiffs' medical causation expert, may be deemed qualified to testify about the alleged *temporal* association between keyboard use and CTS, this testimony cannot bridge the quantum leap which Cunitz's assumptions mandate. Cunitz never met the plaintiffs in the case at bar, nor did he ever independently examine their workstations or keyboards at issue. D.I. 310, Ex. A-121. He further concedes that he is not addressing any alleged defect in the design of the keyboards used by plaintiffs and, significantly, agrees that he is not qualified to express any opinion with regard to the alleged causal association between typing on any keyboard and the development of CTS or any other physical injury. D.I. 310, Ex A-12-22, 131, 141-42. Moreover, Cunitz fails to identify specific warnings which would address his concerns about the keyboards, stating in his deposition that "that's well beyond anything I would ever be asked to do." D.I. 310, Ex. A-122. And he does not attest that any such warning would have prevented the alleged injuries suffered by plaintiffs, as evidenced by the following colloquy during his [*131] deposition:

> Q: Well, are you assuming or do you know that carpal tunnel syndrome can be prevented if the user warnings that you would regard as appropriate?
>
> A: I have assumed in my third assumption that they [sic] were things to tell people that would make a difference.

D.I. 310, Ex. A-136.

The Schneck court addressed a very similar proffer of testimony by a "warnings" expert, with the same dearth of supporting evidence. In Schneck, "warnings" expert Dr. Samuel Glucksberg ("Glucksberg") submitted a report "in which he stated that 'adequate and timely warnings and instructions on the safe use of keyboards to users and to supervisors would significantly reduce the risk of repetitive stress injuries in the work place.'" Schneck Op. at 44. In excluding Glucksberg as an expert witness, the Schneck court reasoned:

> In the present matter, Dr. Glucksberg suggests that warnings are necessary to provide product users with knowledge that would avoid or minimize the risk of injury. *See Glucksberg* Report at 4. He states that "users should be specifically warned about those [design] deficiencies and the risk that they pose for repetitive stress injuries." [*132] *Id.*--However, he provides no foundation for the premise that there are "design deficiencies" that pose a risk of injury. Instead, he simply assumes that is so. Moreover, whether users should be warned is a legal issue. Dr. Glucksberg also opines that "adequate warnings [and] instructions . . . can reduce the incidence of repetitive stress injuries to people at risk." *Id.* At 5. This is a medical issue about which he is unqualified to render an opinion. Such an opinion should be given by a medical causation expert, not a psychologist. His opinion assumes there is, in fact, some evidence that has been shown to reduce this alleged risk; however, there is no evidence presented by Dr. Glucksberg to support this assumption. Dr. Glucksberg continues by stating that warnings should be given to "specify the nature and extent of the potential injuries, namely repetitive stress injuries." *Id.* This begs the question of whether there is evidence of a danger posed by the IBM machines to require such a warning.
>
> Dr. Glucksberg simply assumes that there is scientific evidence of a danger posed by the product giving rise to a duty to warn and that effective remedial meas-

> ures exist. It [*133] is undisputed that IBM did not provide plaintiff [sic] with the kind of warnings plaintiffs claim they should have been given. This is not a case where the adequacy of a particular warning is at issue. Rather, the issue is whether the risk of harm even exists to necessitate a warning . . . Thus, IBM's motion to exclude Dr. Glucksberg's testimony *in limine* is granted.

Schneck Op. at 44-45. See also *Dennis, 927 F. Supp. at 159* (excluding Dr. Glucksberg as an expert on warnings).

Schneck thus denied the proffer of Glucksberg's expert testimony based on the same glaring deficiencies in supporting evidence that this Court now faces with regard to Cunitz. In light of these circumstances, and where it is well recognized that [HN28] an expert opinion must be based on facts, rather than premised on unsupported assumptions and speculation, the Court recommends that Cunitz's testimony be excluded in its entirety. n42

> n42 Plaintiffs and defendant submit contradictory decisions from other jurisdictions admitting and excluding, respectively, Cunitz's testimony as a "warnings" expert. While the Court has reviewed the opinions and the reasoning contained therein, which in some instances follows the rationale espoused by this Court, it recognizes that the opinions cited do not serve as controlling case law.

[*134]

E. Extraneous Arguments Regarding the Admissibility of Plaintiffs' Expert Testimony

Plaintiffs submit two further arguments beyond the Daubert analysis regarding the admissibility of their experts' testimony. Specifically, they contend that: (1) where a Minnesota state court reviewing a similar RSI action allowed plaintiffs' experts to testify upon analysis under the more rigorous Frye standard, the testimony should necessarily be admitted in the case at bar; and (2) plaintiffs' expert testimony is subject to judicial notice by the Court. n43 D.I. 322 at 36-41. Defendant refutes these contentions, citing the Schneck opinion, which squarely rejected the plaintiff's same evidentiary arguments. D.I. 334.

> n43 The Schneck court also rejected plaintiffs' arguments that the reliability of a physician's testimony based on differential diagnosis, the testimony of their design defect expert and the issue of causation are subject to judicial notice and the court therefore need not perform the Daubert analysis. See Schneck Op. at 50-52.

[*135]

With regard to the plaintiffs' success under the Frye standard applied by the aforementioned Minnesota state court in Urbanski v. IBM, this Court concurs with Schneck that:

> while the Urbanski court found that the proffered testimony "may meet [Frye's] requirements of reliability and trustworthiness," Urbanski slip op. at 9 (citations omitted), such findings are by no means persuasive as to whether the experts in this case pass muster under Daubert/Paoli II. Plaintiffs' suggestion that this Court is somehow bound by the Minnesota state court decision in Urbanski is wholly without merit.

Schneck Op. at 47-48.

As for plaintiffs' alternative argument that the expert testimony is subject to judicial notice, the Court finds this novel argument unsupported by case law and therefore rejects same. As the Schneck court so aptly stated:

> plaintiffs argue that "the scientific techniques, implied in this case, epidemiology, differential medical diagnosis, and product design evaluations, are based on 'well established propositions,' and 'are subject to judicial notice.'" Plaintiffs have not, and indeed can not (sic), come forward with [*136] any authority to support this novel argument. In fact, in each case cited by plaintiffs, the proffered evidence was subjected to some type of judicial scrutiny and was not received into evidence without the requirements of formal proof. Plaintiffs' unsubstantiated argument, therefore, fails to defeat IBM's motion for summary judgment.

Schneck Op. at 50 (citations omitted).